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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/373,585	08/13/1999	NOBUHIKO OGURA	Q55432	2737

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EXAMINER
LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
1634	19

DATE MAILED: 08/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/373,585	Ogura
Examiner	**Art Unit**
Frank Lu	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 28, 2002* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *6, 7, and 14-21* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *6, 7, and 14-21* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 5/28/2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/373,585 is acceptable and a CPA has been established. The claims pending in this application are claims 6, 7, and 14-21. The following rejections are based on amendment after the final rejection filed on October 25, 2001. Rejection and/ or objection not reiterated from the previous office action has been withdrawn. An action on the CPA follows.

Claim Rejections - 35 U.S.C. § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 6, 7, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matson *et al.,* (US Patent No.5,429, 807, Published on July 1995) in view of and Yamamoto (US Patent No. 5,145,548, published on September 8, 1992) and Heyneker (US Patent No. 6,057, 100, filed on June 6, 1997).

Matson *et al.,* teach method and apparatus for creating biopolymer arrays on a solid support surface.

As shown in Figures 1 and 7, an applicator in the form of a thick plate having in a surface a plurality of parallel open channels was used for applying reagents to the surface of a solid phase support material. The applicator was positioned over the solid support material with the surface having the channels sealed against the material surface. For each channel, reagents for synthesis were introduced sequentially into one end of the channel and collected from the other end of the channel. Biopolymers such as oligonucleotides were synthesized on the surface of the material that was exposed to the reagents flowing through the open channel, having a specific sequence which depended on the particular sequence of reagents supplied to the particular channel. A parallel one-dimensional array of biopolymers were thus formed on the support material, where each element of the array contained a population of biopolymers having identical sequence. The different channels might correspond to different biopolymer sequences distributing reagents accordingly to the different channels using an appropriate reagent distribution system. Here a plurality of parallel open channels could be considered as plurality of applicators described in claim 6.

Another parallel one-dimensional matrix or array of biopolymers could be formed at an angle to the previous array by rotating the applicator with respect to the solid support material and carrying out synthesis procedure. At each overlapping region of the two parallel arrays, a cell of biopolymers were formed which each comprised a strand from the second array serially connected to a strand from the first array. The result was a two-dimensional array of biopolymers of different sequences at each discrete cell as shown in Figure 8. Further rotation of the applicator and conducting further synthesis could be carried out as desired to build up longer biopolymers or specific arrays of various combinations of biopolymers. The arrays of discrete cell containing different biopolymers could be used to conduct hybridization reaction analysis of a biological sample (see column 2). Positioning means for positioning the applicator (see column 8, claim 1) could be considered as a conveyor as described in claim 6. Note that, although Matson *et al.*, did not show to apply a plurality of cDNAs on the sheet-like substrate as described claim 7, in the absence of convincing evidence to the contrary the claimed invention, it have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use this apparatus on the sheet-like substrate immobilized cDNA since it is well known that a plurality of cDNAs could form an array (see Heyneker, US Patent No. 6,057, 100, filed on June 6, 1997).

Matson *et al.*, do not disclose to use a cutting means to sectioned a substrate that immobilizes a plurality of known specific binding agents into a plurality of strips.

Yamamoto does teach a cutting means to sectioned a substrate into a plurality of strips (see last paragraph of column 9 and first paragraph of column 10 and Figure 13).

Heyneker does teach to section or piece of the array which contains at least a portion of every oligonucleotide-bearing stripe (see column 6, second paragraph).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have cut a sheet-like substrate that immobilized a plurality of known specific binding agents into a plurality of strips as suggested by Heyneker using a cutting means as suggested by Yamamoto. One having ordinary skill in the art would have motivated to modify the apparatus of Matson *et al.*, and add a cutting means into the apparatus because a "strip" or "test strip" which contained at least a portion of every oligonucleotide on a nucleic acid array could reduce experimental cost and would be much easy to handle. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to combine these prior arts together because all of these prior arts are well known and are easy to use.

5. Claims 14-20 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stern *et al.,* (US Patent 5,631,734, filed on February 10, 1994).

Stern *et al.* teach method and apparatus for detection of fluorescently labeled materials. Figure 1a schematically illustrated a device used to detect fluorescently labeled targets on a substrate. Substrate 230 comprised a number of presynthesized probes on its surface 231. The substrate on which the sequences were formed might be composed from a wide range of material, either biological, nonbiological, organic, inorganic, or a combination of any of these,

existing as particles, strands, precipitates, gels, sheets, tubing, spheres, containers, capillaries, pads, slices, films, plates, slides, etc. The substrate might have any convenient shape, such as a disc, square, sphere, circle, etc. The substrate was preferably flat but may take on a variety of alternative surface configurations. For example, the substrate might contain raised or depressed regions on which a sample was located. The substrate and its surface preferably formed a rigid support on which the sample could be formed. The substrate and its surface were also chosen to provide appropriate light-absorbing characteristics (column 3, last paragraph).

A light source 100 generated a beam of light to excite the fluorescein labeled targets in the flow cell. The light source might be a argon laser that generated a beam having a wavelength of about 488 nm, which in some embodiments might be a model 2017 or model 161C manufactured by Spectra-Physics (column 5, fourth paragraph). In response to the excitation light, fluorescein labeled targets in the flow cell fluoresce light had a wavelength greater than about 520 nm. The fluorescence would be collected by the microscope objective 140 and passed to optical lens 130. In practice, light collected by microscope objective contained both fluorescence emitted by the fluorescein and 488 nm laser light reflected from the surface 231 (column 6, fifth paragraph).

Flow cell 220 was mounted on a x-y-z translation table 250. X represented the horizontal direction; y represented the vertical direction; and z represented the direction into and away from the microscope objective such that focusing could be performed. Movement of the translation table was controlled by computer 190 (see third paragraph in column 5 and second paragraph in column 11). The x-y-z translation table could be considered as a conveyor described in claim 14.

Figure 1c illustrated an alternative embodiment of the fluorescence detection device which was similar to the embodiment shown in Figure 1a. Two color detection were required when two different types of targets, each labeled with a different dye, were exposed to a substrate synthesized with probes. In some embodiments, fluorescein and rhodamine dyes might be used to label two different types of targets respectively. Typically, each dye would have a fluorescence peak at different wavelengths (column 8, fourth paragraph). According to the embodiment in Figure 1c, two fluorescence colors could be detected by employing a second dichroic mirror, photomultiplier tube and associated lens, confocal pinhole and filter. The embodiment illustrated in Figure 1c might be expanded by one skilled in the art to detect more than two fluorescence colors by employing an additional dichroic mirror, photomultiplier tube and associated lens, confocal pinhole and filter for each additional fluorescence color to be detected (column 9, second paragraph).

During the detection, data were acquired continuously along a line which was broken up into data points or pixels (column 9, third paragraph). The system operation was dependent on several test parameters such as: a) temperature of the substrate; b) number of scans to be performed; c) time between scans; d) refocus between scans; e) pixel size; f) scan area; and g) scan speed (column 10, second paragraph). The scanning system could be considered as the part of the detection system. Note that: (1) although the detection apparatus had been illustrated primarily herein with regard to the detection of marked targets, it would readily find application in other areas. For example, the detection apparatus disclosed herein could be used in the fields of catalysis, DNA or protein gel scanning, and the like (column 16, last paragraph). Such

disclosure reasonably suggests that this system can be used to detect nucleic acid hybridization wherein cDNAs are immobilized on strip-like substrate as described in claims 15 and 18; (2) although the patent did not directly state that the scanning system could causes the exciting light to linearly scan the strip-like test piece in the longitudinal direction, in the absence of convincing evidence to the contrary the claimed invention, this limitation is considered as inherent to the reference taught by Stern *et al.,* since the scanning system could cause the exciting light to linearly scan the strip-like test piece along multiple axes and the longitudinal direction can be considered as one of species of multiple directions (multiple axes) during the scanning process; and (3) since this system could be used to detect the interaction between unlabeled substrate and two different fluorescence-labeled targets (see column 8, fourth paragraph), such disclosure reasonably suggests the use of one or more fluorescence-labeled substrates.

Conclusion

6. This is a CPA of applicant's earlier Application No. 09/373,585. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. No claim is allowed.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
August 5, 2002

ETHAN C. WHISENANT
PRIMARY EXAMINER